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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,991	02/15/2000	Frank Uhlmann	0652.2040000/REF	3282
7590	07/23/2004		EXAMINER	FRONDA, CHRISTIAN L
Sterne Kessler Goldstein & Fox PLLC Attorneys at Law 1100 New York Avenue N W Suite 600 Washington, DC 20005-3934			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED: 07/23/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/500,991	Applicant(s)	UHLMANN ET AL.
Examiner	Christian L Fronda	Art Unit	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36,37,40,41,43,44,46-49,58 and 59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36,37,40,41,43,44,46-49,58 and 59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 February 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2004, has been entered.
2. Claims 36, 37, 40, 41, 43, 44, 46-49, 58, and 59 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 36, 37, 40, 41, 43, 44, 46-49, 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed May 6, 2004, have been fully considered but they are not persuasive. Applicants' position is that the specification provides guidance for generating fragments and variants of SCC1 that can be cleaved by separin and assay for determining separin activity using SSC1, and relevant identifying characteristics of members of the claimed genus have been disclosed. The Examiner respectfully disagrees for the reasons of record and for the following reasons stated below.

The claims are genus claims which are directed toward a genus of methods for identifying separin inhibitors using any substrate. The claims encompass a highly variant genus of substrates with widely differing structural, chemical, and physical characteristics. The genus is highly variable because a significant number of structural differences between genus members is permitted.

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While the specification discloses a human SCC1 protein substrate consisting of the amino acid sequence of SEQ ID NO: 1, the claims also encompass fragments or variants thereof which have structural, chemical, and physical characteristics that are different from the disclosed protein substrate consisting of the amino acid sequence of SEQ ID NO: 1. The specification does not provide a written description for these fragments or variants of SEQ ID NO:1 which can be used in the claimed method. There is no disclosure of any particular structure to function/activity relationship that is recited in the claims for the genus of fragments and variants of said protein substrate of SEQ ID NO: 1.

The disclosed protein substrate consisting of the amino acid sequence of SEQ ID NO: 1 used in the claimed method is not representative of the entire genus of methods that is claimed. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite a method using a SCC1 protein substrate consisting of SEQ ID NO: 1 or a fragment thereof which can be cleaved by separin may overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 36, 37, 40, 41, 43, 44, 46-49, 58, and 59 are again rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims do not recite steps that show how the inhibiting effect of the test compound inhibits sister chromatid separation in eukaryotic cells. It appears that the method steps describe a method for identifying a compound that inhibits the proteolytic activity of separin instead of a method for identifying a compound that inhibits sister chromatid separation. Applicants have not presented arguments to traverse this rejection.

Conclusion

7. No claims are allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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